

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2004/011228

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/426 A61P17/06 A61P17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61P A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE, PASCAL

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| X | PICCIONI ET AL: "Experimental study on some properties of N-carbethoxy-4-thiazolidine" RIVISTA ITALIANA DI BIOLOGIA E MEDICINA, vol. 11, no. 3-4, 1991, pages 123-127, XP001205351 page 124, right-hand column, paragraph 4 | 1-5 |
| P, X | WO 03/084553 A (SINCLAIR PHARMACEUTICALS LIMITED; MASTRODONATO, MARCO; CIATTINI, ROBER) 16 October 2003 (2003-10-16) page 1, line 1 - line 8 claims 1,6,10,11,16,19,22-25 ----- -/-- | 1-6, 13-17 |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

25 February 2005

Date of mailing of the international search report

24/03/2005

Name and mailing address of the ISA

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|--------------------------------|
| P, X | <p>ZHAI ET AL: "Efficacy of a Topical Agent, MAS063D ('Atopiclair'), in the Treatment of Sodium Lauryl Sulphate-Induced Irritant Contact Dermatitis"</p> <p>EXOGENOUS DERMATOLOGY, vol. 2, no. 6, 2003, pages 301-305, XP009044377</p> <p>page 301, right-hand column, paragraph 4 - page 302, left-hand column, paragraph 3 page 304, left-hand column, paragraph 1 page 305, right-hand column, paragraph 1</p> <p>-----</p> | <p>1-6, 13, 14, 16, 17</p> |

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Information on patent family members

International Application No

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| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
|---|---|---------------------|----------------------------|---------------------|
| WO 03084553 | A | 16-10-2003 | IT MI20020756 A1 | 09-10-2003 |
| | | | AU 2003226754 A1 | 20-10-2003 |
| | | | BR 0309061 A | 01-02-2005 |
| | | | CA 2481770 A1 | 16-10-2003 |
| | | | WO 03084553 A1 | 16-10-2003 |
| | | | EP 1494692 A1 | 12-01-2005 |
| ----- | | | | |

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 13 JAN 2006

WIPO

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|--|--|---|--|--|
| Applicant's or agent's file reference JWJ01162WO | | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/EP2004/011228 | | International filing date (day/month/year) 07.10.2004 | | Priority date (day/month/year) 09.10.2003 |
| International Patent Classification (IPC) or national classification and IPC A61K31/426, A61P17/06, A61P17/00 | | | | |
| Applicant SINCLAIR PHARMACEUTICALS LIMITED et al. | | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 1 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | | |
| Date of submission of the demand 05.08.2005 | | Date of completion of this report 12.01.2006 | | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | | Authorized Officer Albayrak, T Telephone No. +49 89 2399-7549 | | |



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

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PCT/EP2004/011228

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-17 as originally filed

18-20 received on 04.08.2005 with letter of 04.08.2005

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
 - ☒ claims Nos. 13-15
because:
 - ☒ the said international application, or the said claims Nos. 13-15 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination (specify):
see separate sheet
 - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☐ no international search report has been established for the said claims Nos.
 - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
 - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
 - ☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------------|
| Novelty (N) | Yes: Claims | 6-17,20 |
| | No: Claims | 1-5,18,19 |
| Inventive step (IS) | Yes: Claims | 6-17,20 |
| | No: Claims | 1-5,18,19 |
| Industrial applicability (IA) | Yes: Claims | 1-12,16-20 |
| | No: Claims | - |

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and /or

2. Non-written disclosures (Rule 70.9)

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

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Re Item III

The subject-matter of claims 13-15 is related to subject-matter considered to be covered by the provisions of Rule 67.1 (iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4) (a) (I) PCT).

For the assessment of the present claims 13-15 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Claims 1-12 and 16-17 are considered industrially applicable.

Re Item V

Reference is made to the following documents; unless otherwise indicated, reference is made to the relevant passages emphasized in the Search Report.

D1: PICCIONI ET AL: "Experimental study on some properties of N-carbethoxy-4-thiazolidine" RIVISTA ITALIANA DI BIOLOGIA E MEDICINA, vol. 11, no. 3-4, 1991, pages 123-127, XP001205351

1. Novelty

D1 discloses a pharmaceutical composition comprising telmestaine (SPA-PU 795 = N-carbetossi-4-thiazolidin carbosillico = N-carbethoxy-4-thiazolidin carboxylic acid) in a phosphate-buffer.

- A-phosphate buffer is a pharmaceutically acceptable carrier.
- The composition is suitable for topical administration.
- A lotion is a liquid preparation for external cosmetic or pharmaceutical use.
- A surfactant is a compound showing an activity at the surface of a liquid when dissolved in said liquid. Phosphate is therefore considered to be a surfactant.
- A shampoo is a composition suitable to wash hair.

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REPORT ON PATENTABILITY
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- The composition of D1 discloses neither proanthrocyanidin nor glycyrrhetic acid.

Thus, all technical features of claims 1-5 and 18-19 are disclosed in D1. These claims therefore lack novelty under Art. 33(2) PCT.

Remaining claims 6-17 and 20 appear to fulfill the criteria of Art. 33(2) PCT.

2. Inventive step

D1 does not disclose or fairly suggest the use of telmestine for the preparation of a topical medicament for treating dermatological diseases.

Thus, claims 6-17 and 20 are considered inventive under Art. 33(3) PCT.

Re Item VI

The following document could become relevant in some contracting states after entering the national/regional phase(s):

D2: WO 03/084553 A (SINCLAIR PHARMACEUTICALS LIMITED;
MASTRODONATO, MARCO; CIATTINI, ROBER) 16 October 2003 (2003-10-16)

18. A pharmaceutical composition according to any of claims 1 to 6, wherein the composition does not comprise proanthrocyanadin or glycyrrhetic acid.

19. A composition according to claim 1 or claim 18, in the form of a shampoo.

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20. Use of a composition according to claim 18, in the manufacture of a medicament for the treatment of a dermatological disease or disorder.